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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,044	01/05/1999	ALLAN S. HOFFMAN	UWS-102	1587

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/226,044

Applicant(s)

Hoffman

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34-100 is/are pending in the application.
- 4a) Of the above, claim(s) 91-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 34-90 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

**1. Applicant's election without traverse of species in claims 34-90 in Paper No. 25 is acknowledged.**

**Claims included in the prosecution are 34-90.**

#### ***Claim Rejections - 35 U.S.C. § 102***

**2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**3. Claims 34-35, 37-43, 47-48, 50, 53, 66, 68, 70-75, 77-81 and 83-86 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14142.**

**WO discloses a method of drug delivery using polymeric carriers. The drugs include anti-cancer drugs and photoactivatable drugs. The polymeric compounds include copolymers of various acrylamides, acrylic acid, methacrylic acid, polysaccharides and polyamino acids; the compositions further contain a targeting agent such as an antibody (note the abstract, pages 6-7, 10-11, 15, 18, Examples and claims).**

**(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**

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4. Claims 34-43, 47-50, 53, 57-59, 64-81 and 83-86 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/09068 of record.

WO 09068 teaches stimuli-responsive polymer systems for drug delivery (note the abstract and the entire patent). The composition contains a the polymer chain which is responsive to changes in pH, temperature, light or other stimuli and a molecule such as a hormone or an enzyme (abstract, pages 10-27, in particular pages 17-23; 36 and 50-54).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 34-35, 57-61, 70-74, and 84-86 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg (5,876,989).

Berg discloses compositions and a method of releasing molecules into the cytosol. The molecules are taken up endosomes and released into cytosol by an external stimulus such as light activation of photosensitive compounds. The compositions contain a carrier, a toxin (gelonin) or nucleic acid and a photosensitive agent (note the abstract, columns 4-5, Examples and claims).

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***Claim Rejections - 35 U.S.C. § 103***

**6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**7. Claims 37-39, 43-46, 48, 51-52, 60-69, 75-79, 81-82, and 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/14142 or WO 97/09068.**

**The teachings of WO 93 and WO 97 have been discussed above. These references teach copolymers obtained from the monomers of acrylic acid and methacrylic acid. They do not teach ethylacrylic acid, propylacrylic acid and butylacrylic acid. However, since these are homologues of methacrylic acid, it is deemed obvious to one of ordinary skill in the art to the claimed monomers since homologues are expected to behave the same way. The references do not explicitly teach the behavior of the polymers with respect to the pH changes. However, since the references teach the same polymers, it would have been obvious to one of ordinary skill in the art that they would behave the same way when the pH is changed. WO 93 and 97 do not teach the claimed active agents such as toxins; however, it would have been obvious to one of ordinary skill in the art to use any active**

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agent including the claimed toxins since the principle of release of the active agent in the cytosol is the same irrespective of the active agent.

8. Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/14142 or WO 97/09068, further in view of Berg (5,876,989).

As pointed out above, WO 93 discloses a method of drug delivery using polymeric carriers. The drugs include anti-cancer drugs and photoactivatable drugs. The polymeric compounds include copolymers of various acrylamides, acrylic acid, methacrylic acid, polysaccharides and polyamino acids; the compositions further contain a targeting agent such as an antibody (note the abstract, pages 6-7, 10-11, 15, 18, Examples and claims).

As also pointed out above, WO 97 teaches stimuli-responsive polymer systems for drug delivery (note the abstract and the entire patent). The composition contains a the polymer chain which is responsive to changes in pH, temperature, light or other stimuli and a molecule such as a hormone or an enzyme (abstract, pages 10-27, in particular pages 17-23; 36 and 50-54).

What is lacking in these references is the teaching that the active agent to be a toxin such as those claimed in instant claims.

Berg cited above discloses compositions and a method of releasing molecules into the cytosol. The molecules are taken up endosomes and released into cytosol by an external stimulus such as light activation of photosensitive compounds. The compositions contain a

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carrier, a toxin (gelonin) or nucleic acid and a photosensitive agent (note the abstract, columns 4-5, Examples and claims).

In essence WO publications and Berg deal with the same concept: that is the compositions entering the endosomes and subsequently released in the cytosol. Therefore, it would have been obvious to use any active agent including the claimed toxins in WO 93 or 97 with the expectation of similar release sine Berg teaches that toxins such as gelonin can be administered using the same principle.

9. Claim 36 is are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/14142 or WO 97/09068 in view of Shapland (5,807,306) of record.

The teachings of WO 93 and 97 have been discussed above. What is lacking in these references is the teaching of the stimulus being ultrasound.

Shapland while disclosing drug delivery systems teaches that the drug could be released internally using ultrasound or iontophoresis (note the abstract, column 16 and claims).

The use of ultrasound as the external stimulus in the teachings of WO 93 or 97 would have been obvious to one of ordinary skill in the art since the reference of Shapland teaches that release of the drug could be accomplished by using an external stimulus such as ultra sound or iontophoresis. One of ordinary skill in the art would be motivated to used ultrasound with the expectation of the drugs in WO 93 or 97.

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**10. Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/14142 or WO 97/09068 in view of Anderson (Bioconjugate Chemistry, 4, 1993, pp. 10-18) of record.**

**The teachings of WO 93 and 97 have been discussed above. In essence these references teach the polymer-drug combination and also the attachment of peptides the polymers. The composition in these references also respond to the external stimuli, thus releasing the drug in the cytosol. What is lacking in these references is the teaching that the polymers be conjugated to GALA peptide.**

**Anderson teaches that GALA peptides enhance the internalization of antibodies in tumor cells when the antibodies are attached to GALA peptides (note the abstract). It would have been obvious to one of ordinary skill in the art to attach GALA to the polymers of WO 93 and 93 since such an attachment would enhance the internalization of the complex in the tumor cells and release the drug in the cytosol with the subsequent application of the external stimuli.**

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**11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

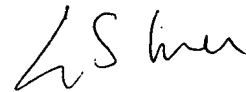
**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**